K000369

MAR 3 0 2000

510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k):

AJW Technology Consultants, Inc.
962 Allegro Ln.
Apollo Beach, FL 33572

Phone: 813-645-2855
Fax: 813-645-2856

Contact Person: Art Ward

Date of Summary: January 15, 2000

Trade Name: MED-PRO VACUFLOW+ Blood Collection Set

Classification Name: Needle, Hypodermic, Single Lumen
21 CFR Section 880.5570

Predicate Device:

K935505	Winged Collection Set	Kawasumi
K972404	Vacutainer BCA	Becton Dickinson

Device Description/ Comparison: The MED-PRO VACUFLOW+ is a blood collection set comprised of a winged needle, ¾ inch long in 21, 23 and 25 gauge with a 12 inch sample collection tube with multi-sample adapter and optional tube holder. The device is sterile, single patient use.

Intended Use: The VACUFLOW+ Blood Collection Set is a sterile, multiple sample, single use device. One end of the set has attached a multi-sample luer adapter, which can and usually is connected to a tube holder from which blood is drawn through a vacutainer and the other is a needle for performing venipuncture for blood collection.

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510(K) Summary
Differences and Similarities

As reviewed in Section 9 the VACUFLOW+ Blood Collection Set is fundamentally similar to the predicate devices. This summary reviews the:

Intended Use
Applications
Usage Location
Technological characteristics

Intended Use:

Both the VACUFLOW+ and predicate devices have the same intended use for the collection of blood by venipuncture.

Applications:

Both the MED-PRO and predicate products are used for the collection of blood in clinical settings.

Usage Location:

The VACUFLOW+ and predicate devices are designed for use within a laboratory, hospital, physician's office or other clinical setting.

Technological Characteristics:

These products have very similar technology in their components.

Similarities:

All devices are sterile, single patient use.
The stainless steel venipuncture needle is ¾" long and available in different gauge sizes.
The MED-PRO and Kawasumi device both have a winged needle and 12" sample tubing with Multi-Sample luer adapter.
The MED-PRO device with optional tube holder is similar to the Becton Dickinson device's tube holder.
Devices are all packaged in either 25 or 50 unit packs.

Differences:

The MED-PRO unit is packed in one tyvek sided pouch, the B-D unit in a two tyvek sided pouch and the Kawasumi unit has one tyvek strip in the center of the pouch.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 0 2000

Med-Pro Technologies, Inc.
C/O Mr. Arthur J. Ward
AJW Technology Consultants, Inc.
962 Allegro Lane
Apollo Beach, Florida 33572

Re: K000369
Trade Name: Med-Pro Vacuflow+ Blood Collection Set
Regulatory Class: II
Product Code: FMI
Dated: March 17, 2000
Received: March 22, 2000

Dear Mr. Ward:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4690. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000369

Device Name: VACUFLOW+ Blood Collection System

Indications For Use:

The VACUFLOW+ Blood Collection Set is a sterile, multiple sample, single use device. One end of the set has attached a multi-sample luer adapter, which can and is usually connected to a tube holder from which blood is drawn through a vacutainer and the other is a needle for performing venipuncture for blood collection.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Patricia Cascito (Optional Format 1-2-96)
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000369